IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	WISNIEWSKI et al.	Group Art Unit:	3743
Serial No.	:	08/895,936	Examiner :	John Ford
Filed	:	July 17, 1997		
For	:	FREEZING AND THAWING VESSEL WITH THERMAL BRIDGE		

Commissioner for Patents
Washington, D.C. 20231

SECOND DECLARATION OF RICHARD WISNIEWSKI

1. I am one of the inventors of the above-referenced United States patent application. I am also a named inventor of six U.S. Patents relating to cryopreservation of biopharmaceuticals and numerous pending patent applications. I make the statements herein to the best of my own personal knowledge.

2. I received degrees in Mechanical Engineering and Chemical Engineering from Warsaw Technical University in Warsaw, Poland in 1971. I have over 26 years of experience in applied research, process and product development, process control, equipment and device design, industrial facility design and project and team management in the biopharmaceutical field.

3. I am a co-founder and currently the Chief Technology Officer of Integrated Biosystems, Inc.

4. Prior to my current position, I have held senior engineering and management positions with Wyeth-Ayerst, Genentech, Inc., Bepex Corporation and Ares Serono. While at Genentech, Inc., I was a Principal Process Engineer responsible for pioneering work in

the design of equipment and processes for biopharmaceutical manufacturing, including systems for cryopreservation, chromatography, filtration and bioreactors and aseptic processing used in large scale production. I do not currently work for Genentech and have not worked for Genentech for over a decade, since January of 1991.

5. While I was working for Genentech, Inc., I co-published, with Vincent L. Wu, an article entitled "Large-Scale Freezing and Thawing of Biopharmaceutical Drug Product" for the Advanced Technologies For Manufacturing Of Aseptic & Terminally Sterilized Pharmaceuticals & Biopharmaceuticals convention during the Proceedings of the International Congress in 1992 ("the 1992 article"). This 1992 article is similar to the 1996 article previously disclosed to the Patent Office during the prosecution of the above-reference application.

6. I have read and am familiar with the most recent Office action mailed January 29, 2003 in connection with the above-identified application.

7. In the specification of the above-identified application, the first two paragraphs under the heading "2. Description of the Prior Art" refers to the Genentech device disclosed in the 1992 Wisniewski and Wu publication. Other than the 1992 Wisniewski and Wu publication, I do not have any further documents relating to the Genentech device, including any specifications on the distance between the fin tip and the interior vessel wall.

8. However, to the best of my knowledge, Exhibits B, C and D of my first declaration reasonably resemble the temperature distribution of the 1992 Genentech container and the drawing of the Genentech device in the 1992 article accurately represent a scaled down version of the device. Thus, the distance depicted in the 1992 article reasonably represents the relationship between the distance between the fins and the interior wall. Although I cannot remember the exact distance between the fin tip and the interior wall of the Genentech device, I know that this distance was greater than 4 inches. When I

designed the Genentech device, the distance between the fin tip and the interior vessel wall was not an important parameter. The fins of the Genentech vessel were small and thin, as shown in the 1992 Wisniewski and Wu publication, and designed only to aid the freezing around the loop pipe in order to increase the relatively small surface area of the pipe (e.g. adding more cold surface area). No thermal bridge was formed by the biopharmaceutical material between the fin tip and the interior wall of the Genentech device.

9. In the specification of the above-identified application, the third paragraph under the heading "2. Description of the Prior Art" refers to a container having ribs welded to the core and the interior wall of the vessel. Since the ribs were connected to both the internal core and the interior wall of the vessel, no thermal bridge can be formed by the medium between a fin tip and the interior wall of the vessel because there is no gap between the ribs and the interior wall of the vessel. Heat transfer occurs only through the external wall of the vessel. Although not relevant to the particular freezing of biopharmaceutical materials, an example of such a vessel is shown in U.S. Patent Nos. 2,441,376 to Stiening and 2,129,572 to Finnegan. To the best of my knowledge, such vessels were used in heat storage devices for, e.g., paraffin and comestibles.

10. Some time ago, I attended an Examiner's interview at the U.S. Patent and Trademark Office with David Abraham, Esq. from the law firm Wilson Sonsini Goodrich & Rosati. During that interview, I recall discussion of the Basel Pharmaceutical Meeting/Conference presentation document (Proceedings of the International Congress), which contained a copy of the 1992 Wisniewski and Wu publication. This presentation document was attached to my first declaration as Exhibit A. To the best of my knowledge, no actual device or other documents were discussed or presented at the meeting because no such device or documents were in our possession.

11. I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in this Affidavit is true and correct.

February 26, 2003

Richard Wisniewski